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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,170	03/26/2004	Mark W. Sleeman	REG 711A	2033

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EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,170	SLEEMAN ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-5, 8, 10-12, 14, 16, 17 and 19-21, drawn to a method of treating diabetes by administering an agent capable of blocking, inhibiting or ameliorating VEGF-mediated activity wherein the agent is an antibody, classifiable in class 424, subclass 130.1.

II. Claims 2-5, 6, 8, 10-14, 16-21, drawn to a method of treating diabetes by administering an agent capable of blocking, inhibiting or ameliorating VEGF-mediated activity wherein the agent is a VEGF trap, classifiable in class 530, subclass 350. Election of this group requires a species election as set forth below.

III. Claims 2-5, 8, 10-12,14, 16, 17 and 19-21, drawn to a method of treating diabetes by administering an agent capable of blocking, inhibiting or ameliorating VEGF-mediated activity wherein the agent is a small molecule, classifiable in class 514, subclass 1.

IV. Claims 2-5, 8, 10-12, 14, 16, 17 and 19-21, drawn to a method of treating diabetes by administering an agent capable of blocking, inhibiting or ameliorating VEGF-mediated activity wherein the agent is a lipid, classifiable in class 435, subclass 6.

V. Claims 2-5, 8, 10-12, 14, 16, 17 and 19-21, drawn to a method of treating diabetes by administering an agent capable of blocking, inhibiting or ameliorating VEGF-mediated activity wherein the agent is a carbohydrate, classifiable in class 514, subclass 23.

VI. Claims 2-4, 7 and 8, drawn to a method of treating diabetes by administering an agent capable of blocking, inhibiting or ameliorating VEGF-mediated activity wherein the agent is an antisense molecule, classifiable in class 514, subclass 44.

VII. Claim 22, drawn to a method of treating diabetes by administering an agent capable of blocking, inhibiting or ameliorating VEGF-mediated activity and a hypoglycemic agent, classifiable in class 424, subclass 93.1.

VIII. Claim 23, drawn to a method of treating diabetes by administering an agent capable of blocking, inhibiting or ameliorating VEGF-mediated activity and a weight loss agent, classifiable in class 424, subclass 93.1.

IX. Claim 24, drawn to an article of manufacturing comprising a VEGF antagonist, classifiable in class 514, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Each of the

inventions use a specific type of agent that are patentably distinct not only because they are different chemical classes of molecules including lipids, proteins, nucleic acids, carbohydrates and small molecules; but also because each acts via different mechanisms including binding to antigens or inhibiting gene expression by activating RNAse H. Invention I treats diabetes with an agent that is an antibody, invention II treats diabetes with an agent that is a VEGF trap, invention III treats diabetes with an agent that is a small molecule, invention IV treats diabetes with an agent that is a lipid, invention V treats diabetes with an agent that is a carbohydrate and invention VI treats diabetes with an agent that is an antisense molecule.

2. Furthermore, examining any of inventions I-VI together would impose a serious search burden. In the instant case, prior art searches of methods of treating diabetes with an agent that is an antibody are not coextensive with prior art searches of methods of treating diabetes with any other type of agent. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-VI together.

3. Claim 1 link(s) inventions I-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Claims 9 and 15 further link inventions I-V. The restriction requirement between the linked inventions

is subject to the nonallowance of the linking claim(s), claim 9 and 15. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Inventions I-VI are unrelated to inventions VII and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Inventions I-VI are methods of treating diabetes solely with a single specific type of agent that modulates VEGF. Inventions VII and VIII are distinct from each other because they are methods of treating diabetes with any agent that modulates VEGF comprising the additional step of treatment with another, different type of therapy, for invention VII a hypoglycemic agent and for invention VIII a weight loss agent. The scope of inventions VII and VIII are different from each of inventions I-VI because of the additional method steps associated with the additional treatment agents and because

inventions VII and VIII encompass use of any agent that modulates VEGF while each of inventions I-VI are limited to use of a specific agent.

5. Furthermore, examining any of inventions I-VI together with either of inventions VII and VIII would impose a serious search burden. In the instant case, prior art searches of methods of treating diabetes with a specific type of agent alone are not coextensive with prior art searches of broader methods of treating diabetes encompassing the use of any type of agent in combination with another type of treatment. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-VI together with either of inventions VII or VIII.

6. Inventions I-VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method could be used with a materially different product, for example diabetes in a mammal can be treated using insulin injections.

7. Furthermore, examining any of inventions I-VIII together with invention IX would impose a serious search burden. In the instant case, prior art searches of methods of treating diabetes with an agent alone or in combination with another type of treatment are not coextensive with prior art searches of compositions of a VEGF antagonist. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-VIII together with invention IX.

Species Election

Claims 6, 13, 18 and 21 are generic to a plurality of disclosed patentably distinct species comprising the VEGF traps recited in each of these claims. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811.

On July 15, 2005, the Central FAX Number will change to 571-273-8300. This new number is already operational and faxes sent to the old number (703-872-9306) will be routed to the new number until September 15, 2005.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
July 8, 2005

JAMES SCHULTZ
PATENT EXAMINER